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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,042	04/21/2004	Trevor Barrowcliffe	674583-2001	7419

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EXAMINER	
ROOKE, AGNES BEATA	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 11/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/829,042	BARROWCLIFFE, TREVOR	
	Examiner	Art Unit	
	Agnes B Rooke	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 13-15* is/are pending in the application.

4a) Of the above claim(s) *9-12,16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 13-15* is/are rejected.

7)☒ Claim(s) *1 and 5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-8 and 13-15 are pending, and Claims 9-12 and 16-17 are withdrawn from the consideration.

Responsive to the Restriction requirement the Applicant elected Invention of group I, claims 1-8 and 13-15 with traverse, filed on October 15, 2004. The Applicant's traversal is on the grounds that the Inventions of groups I-IV are not distinct, and that search and examination of the claims of groups I-IV would not require an undue and serious burden. The Applicant's traversal is fully considered, but it is not found persuasive, because Inventions of groups I-IV are independent and distinct, and have acquired separate status in the art because of their recognized divergent subject matter and different classification. Moreover, search and examination of all Inventions of groups I-IV in one patent application would result in an undue burden on the examiner.

The Restriction requirement is still deemed proper and is therefore made FINAL.

This application claims priority from the United Kingdom 0311465.9 (05/19/2003) and United Kingdom 0318533.7 (08/08/2003). However, it is acknowledged that at this time the priority documents are not available on file, and thus proper submission of the priority documents is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The examiner interpreted Claim 1 as a possible set of different compositions: 1) a composition that contains only FIX; 2) a composition that contains only FVIII; 3) and a composition that contains FVIII and FIX together. The Applicant should clarify in Claim 1 what the claimed invention is and specify the composition claimed.

2. Claims 1, 2, 4 and 13 are rejected because of the improper use of acronyms. The Applicant uses acronyms: "FIXa" and "FVIII," instead the Applicant should state the full name of the product, as for example: "a coagulation factor IXa" and "a coagulation factor VIII" for the purpose of clarity of Claims 1, 2, 4 and 13.

3. Claim 2 provides for the use of FIXa and FVIII in the preparation of a composition, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

4. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 13 states "*A method for potentiating FVIII* [...]." The

meaning of the word *"potentiating"* cannot be ascertained, thus the Applicant must clarify the meaning of the claim.

5. Claims 1 and 5 are objected to because of the improper usage of the word *"which."* The proper word should be *"who."*

6. The title "*Composition*" is objected to, since it does not reflect the nature of the invention.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 2 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Horikoshi *et al.* (U.S. 4,348,384).

Claim 1 of the U.S. 4,348,384 teaches a pharmaceutical composition, which comprises effective amounts of coagulation factor VIII or IX (Claim 1 in the instant invention) in liposomes, which is a phospholipid (Claim 3).

Example 2 of the U.S. 4,348,384 teaches the using of factor VIII in making liposomes composition of factor VIII, and Example 5 teaches the using of factor IX in making liposomes composition of factor IX (Claim 2). See Column 6, lines 18-47, and Column 8, lines 16-52 respectively.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-8, and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horikoshi *et al.* (U.S. 4,348,384).

The U.S. 4,348,384 teaches a pharmaceutical composition suitable for the treatment of haemophilia A or B; which comprises FVIII or FIX (Claims 1, 4-8, and 13-15). See Column 1, lines 6-14. Also, FIX and FVIII are individually and separately incorporated into liposomes (Claims 1, 4-8, and 13-15). See Column 1, lines 6-14 and 65-68. The U.S. 4,348,384 does not teach a pharmaceutical composition of FVIII and FIX together enclosed in liposomes.

Moreover, the U.S. 4,348,384 teaches a dosage of a coagulation FVIII in the range of 500 to 3,000 units per day, and the range of 200 to 2,000 units per day in case of coagulation FIX (Claim 8). See Column 3, lines 39-46.

It would have been obvious for a person of ordinary skill in the art to combine a composition of coagulation FIX with a second composition of FVIII in liposomes (phospholipids), since those compositions are separately used in the art for the treatment of haemophilia A or B. (Claims 1, 4-8 and 13-15). Also, a skilled person in the art would be expected to achieve a great success in designing compositions of FVIII or FIX.

The rejections under 35 USC 103 above are consistent with case law. Applicants are referred to *In re Kerkoven* (205 USPQ 1069) where it was shown to be *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be used for that very same purpose. *Ex Parte Quadranti* (25 USPQ2d 1071) also sets forth this precedent, where the use of materials in combination, each of which is known to function for the intended purpose, is generally held to be *prima facie* obvious. *Ex parte Kucera* (165 USPQ 332) clearly states that synergism has no magical status in rendering otherwise obvious subject matter patentable. Therefore, then, barring unexpected results, one would reasonably expect enhanced, additive, or synergistic activity to be observed by combining the compositions or materials.

Relevant prior art of record:

1. **Knudsen et al., U.S. 0203845A1**, teach a pharmaceutical composition comprising FVII or FVII-related polypeptide and a FIX or FIX-related polypeptide for the prevention or treatment of bleeding episodes, and suggest that many coagulation factors, such as FIX, are recombinantly produced and used in treatment of haemophilia A or B.

2. **Spira et al., U.S. 5,925,739**, teach a pharmaceutical formulation of FVIII or FIX, which has an activity of at least 200 IU/ml up to 1,000 IU/ml, to treat a haemophilia A or B. Also, FVIII is a highly purified recombinant.

2. **Spira et al., U.S. 5,972,885**, teach a pharmaceutical composition comprising recombinant coagulation factor VIII and its use for manufacture of a medicament for a treatment of a haemophilia A or B.

3. **Rose et al., 5,839,443**, teach an assay to monitor antithrombic activity of FIX.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

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